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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/564,884 | 01/17/2006 | Keiko Shibata | 648.45478X00 | 3701 |
| 20457 7590 02/25/2010 ANTONELLI, TERRY, STOUT & KRAUS, LLP 1300 NORTH SEVENTEENTH STREET SUITE 1800 ARLINGTON, VA 22209-3873 | | | | |
| EXAMINER | | | | |
| SASAKI, SHOGO | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 02/25/2010 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,884

Applicant(s)

SHIBATA, KEIKO

Examiner

Shogo Sasaki

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/30/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) 2,12,16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/17/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendments to the claims are acknowledged.

Claim Interpretations

2. Regarding claim 1, the limitations "to which a methanol water mixture and a sample comprising nitropolycyclic aromatic hydrocarbons are sent," "configured to receive the methanol water mixture and the sample from the auto-sampler and configured to separate the sample comprising nitropolycyclic aromatic hydrocarbons into at least four separate nitropolycyclic aromatic hydrocarbons including 1-nitropyrene, 1,3-dinitropyrene, 1,6-dinitropyrene and 1,8-dinitropyrene" and "configured to receive the at least four separate nitropolycyclic aromatic hydrocarbons including 1-nitropyrene, 1,3-dinitropyrene, 1,6-dinitropyrene and 1,8-dinitropyrene from the separation column and to aminate the separated nitropolycyclic aromatic hydrocarbons," which are directed to the manner in which a claimed apparatus is intended to be used do not distinguish the claimed apparatus from the prior art. These limitations do not further structurally limit the claimed apparatus.

In addition, "a methanol water mixture" and "a sample" are not claimed as part of the claimed subject matter. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element. Said recitation does not structurally limit the claims.

Furthermore, the recitation "a separation configured to separate..." is interpreted to mean "a separation column capable of separating..." As stated in previous actions, a separation column specifically designed to separate a sample into four specific isomers of nitro-PAH is not disclosed in the specification. The recitation is somewhat worded in a manner that the separation column specifically separates a sample into four specific isomers of nitro-PAH (Similar to claiming a stationary phase bonded with antigen X to specifically separate antibody X from other protein.). Contrary, the disclosed separation column is a silica gel anchored with C8 stationary phase. The previous office actions

asserted that a hydrophobic silica gel is capable of separating compounds having different hydrophobicities. The examiner maintains his position.

Specification

3. As previously presented, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The separation column specifically designed to separate a sample into four specific isomers of nitro-PAH lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwabuchi (IDS: JP2001-21497: Translation from Patent Abstracts of Japan provided with this office action.).

Regarding claims 1 and 9, Iwabuchi discloses an apparatus for analyzing polycyclic aromatic hydrocarbon comprising (Abstract; Solution; Fig. 4, Fig. 7 and "Description of Notation" in column 6; claim 2; and [0015]-[0018]):

- an auto-sampler (7);
- a separation column downstream of the auto-sampler (9);
- a reduction column downstream of the separation column (17); and
- a fluorescence detector (20); and
- wherein the reduction column is alumina/platinum-rhodium reduction column ([0011]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwabuchi (IDS: JP2001-21497).

Regarding claim 15, Iwabuchi discloses all of the limitations as set forth above.

Iwabuchi does not explicitly disclose the use of C8 column. Iwabuchi uses C18 (ODS) column ([0015]). However the difference between C8 and C18 silica columns are merely in the degrees of hydrophobicities (longer branch of (CH)_x-silane versus shorter ones). The C18 would have been more than capable of separating compounds. The instant application is silent to unexpected result in separating nitro PAHs due to the selection of a particular silica packing columns (Also see paragraph 4 above.).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Iwabuchi and replace C18 with C8 column, since it was within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. Examiner asserts that the substitution would not affect the operability of Iwabuchi's column 9.

Furthermore, the use of a known column material in the system of Iwabuchi would amount to nothing more than a use of a known packing material for a separation column for its intended use in a known environment to accomplish an entirely expected result.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwabuchi (IDS: JP2001-21497) in view of Collins (US 4554132) or Anthony (US 4130474).

Regarding claim 17, Iwabuchi discloses all of the limitations as set forth above.

Iwabuchi does not explicitly teach the ultrasonic agitation for the organic fraction extraction from the particulates.

Collins (C4/L67-C5/L13) and Anthony (Fig. 1, 14; C5/L47-52; and C7/L39-45) both teach the ultrasonic solvent extraction of solubles from solid samples.

It would have been obvious to one having ordinary skill in the art at the time of the invention to apply same technique/device taught by Collins or Anthony, for the purpose of shortening the extraction time. The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art.

10. Claims 1, 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (Determination of mono- and di-nitro polycyclic aromatic hydrocarbons by on-line reduction and high-performance liquid chromatography with chemiluminescence detection).

Regarding claim 1, Li et al. disclose an apparatus for analyzing nitropolycyclic aromatic hydrocarbon comprising (Abstract):

- a reduction column (P178/Experimental);
- a separation column downstream of the reduction column; and
- a fluorescence detector ("2.2.Instrumentation," P178-179/L26-27).

As applicant pointed out, the two columns of Li are in reverse order with respect to the configuration of the apparatus in instant claims.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to reverse the order of two columns in the system taught by Li, since rearrangement of parts or the change in configuration of an invention only involves routine skill in the art. Li discloses that methanol is not appropriate for the detection of the separated compound (P179, column 1), but Li does not say that methanol-water mobile phase would not work with the detection (See P181, column 1, second paragraph). The portion of Li that applicant cited merely states the preference. Examiner asserts that the reconfiguration of the columns in the system of Li would not have affected the operability of Li's system.

Also, Li does not explicitly disclose the use of auto-sampler.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to automate the loading of samples into the separation/analysis device using an auto-sampler, since providing a mechanical or automatic means to replace manual activity which accomplished the same result involves only routine skill in the art.

Regarding claim 15, Li discloses all of the limitations as set forth above.

Li et al. further disclose that the samples containing isomers of aminated nitro polycyclic aromatic hydro carbon are separated by a C18 silica column ("2.5. Diesel exhaust sample," P179/L5-8; Fig. 2; and "2.2.Instrumentation").

Li does not explicitly disclose the use of C8 column. Li uses C18 column. However the difference between C8 and C18 silica columns are merely in the degrees of hydrophobicities (longer branch of $(CH_2)_x$ -silane versus shorter ones). The C18 would have been more than capable of separating compounds. The instant application is silent to unexpected result in separating nitro PAHs due to the selection of a particular silica packing columns (Also see paragraph 4 above.).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Li and replace C18 with C8 column, since it was

within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. Examiner asserts that the substitution would not affect the operability of Li's separation column.

Further, the use of a known column material in the system of Li would amount to nothing more than a use of a known packing material for a separation column for its intended use in a known environment to accomplish an entirely expected result.

Regarding claim 9, Li discloses all of the limitations as set forth above.

Li further disclose that the reduction column contains platinum/rhodium catalyst ("2.3. Online reduction," P178/L1-3).

Li does not explicitly disclose that platinum/rhodium catalyst is on alumina carrier. However the catalyst of Li must also have been provided on an inert carrier. Alumina and silicate, such as zeolites are well known carrier for the catalyst. Choosing from a finite number of possible solutions is obvious.

It would have been obvious to one having ordinary skill in the art at the time of the invention to choose alumina as an inert support for the catalyst, since it was within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

Further, the use of a known inert carrier such as alumina in the system of Li. would amount to nothing more than a use of a known carrier for a metallic catalyst for its intended use in a known environment to accomplish an entirely expected result.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (Determination of mono- and di-nitro polycyclic aromatic hydrocarbons by on-line reduction and high-performance liquid chromatography with chemiluminescence detection) in view of Collins (US 4554132) or Anthony (US 4130474).

Regarding claim 17, Li discloses all of the limitations as set forth above.

Li does not explicitly teach the ultrasonic agitation for the organic fraction extraction from the particulates.

Collins (C4/L67-C5/L13) and Anthony (Fig. 1, 14; C5/L47-52; and C7/L39-45) both teach the ultrasonic solvent extraction of solubles from solid samples.

It would have been obvious to one having ordinary skill in the art at the time of the invention to apply same technique/device taught by Collins or Anthony, for the purpose of shortening the extraction time. The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art.

Response to Arguments

12. Applicant's arguments filed 11/30/2009 have been fully considered but they are not persuasive.

In response to page 6, paragraph 3, the amendment to claim 1 does not change the scope of the claim limitation. Therefore the examiner maintains his position (See paragraph 2, lines 17-26 of this office action.).

In response to page 8, paragraph 2, Iwabuchi in [0016] explicitly discloses that the nitroarenes are sent from column 9 to column 17. The 102 rejections of claims 1 and 9 over Iwabuchi are maintained.

The arguments in pages 9 and 10 are substantially identical to the arguments provided in the reply filed on 8/20/2009 (pages 6 and 7). The examiner has already responded to said arguments. The 103 rejections over Li are maintained.

"Applicant argues that the two columns of Li are in reverse order with respect to the configuration of the apparatus in instant claims. The reduction column of Li is indeed upstream of the separation column. Applicant implies that the system of Li would not be operable since Li states that the methanol-water mobile phase for the reduction column is not appropriate for the detector downstream of the two columns.

However, Li does not say that the methanol-water mobile phase would not work with the detection (See P181, column 1, second paragraph). The portion of Li that applicant cited merely states the preference of the acetonitrile mobile phase in the separation column. Examiner asserts that the reconfiguration of the columns in the system of Li would not have affected the operability of Li's system, because using the

same mobile phase (methanol-water) in both columns would not have been fully compromised the system of Li. One of ordinary skill in the art would have been motivated to rearrange the system of Li and used the same mobile phase in both columns."

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

2/16/2010

/Brian R Gordon/

Primary Examiner, Art Unit 1797